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21839 7590 05/22/2009

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EXAMINER	
BRADLEY, CHRISTINA	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/22/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,291	10/03/2005	Ju-Ock Nam	012679-113	6194

TITLE OF INVENTION: USE OF A PEPTIDE THAT INTERACTS WITH ALPHA V BETA3 INTEGRIN OF ENDOTHELIAL CELL

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	08/24/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

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nonprovisional	YES	$755	$300	$0	$1055	08/24/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
BRADLEY, CHRISTINA	1654	514-013000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☐ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

☐ A check is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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BRADLEY, CHRISTINA	
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1654	

DATE MAILED: 05/22/2009

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/552,291	NAM ET AL.	
	Examiner	Art Unit	
	CHRISTINA BRADLEY	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed 02/16/2009*.

2. ☒ The allowed claim(s) is/are *1,4-7 and 13-17*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Christina Marchetti Bradley/ Examiner, Art Unit 1654	/Cecilia Tsang/ Supervisory Patent Examiner, Art Unit 1654

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. Authorization for this examiner's amendment was given in a telephone interview with Lisa Stahl on 04/28/2009.

3. The application has been amended as follows:

1. (Currently Amended) A method for inhibiting endothelial cell adhesion, endothelial cell migration and/or angiogenesis, comprising administering to a subject in need thereof an effective amount of:

an isolated peptide comprising an amino acid sequence represented by (I, D, E or K)-(E, A or Q)-L-(L, R or A)-(N, D or S)-(A, L, K or I)-(L or Y)-(R, N, L or K)-(Y or N)-H\- (M, I or G)-(V, L, Q or G)-(G, K, T or D)-(R, S, L or E)-(R, A, E or I)-(V, M, T or L)-(L, C or V)-(T, A, G or S);

wherein said subject in need thereof has an angiogenesis-related disease selected from cancer and rheumatoid arthritis.

2-3. (Canceled).

4. (Previously Presented). The method of Claim 1, wherein the isolated peptide comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 23 to SEQ ID NO: 26.

5. (Currently amended) A method for inhibiting endothelial cell adhesion, endothelial cell migration and/or angiogenesis, comprising administering to a subject in need thereof an effective amount of an isolated peptide comprising~~The method of Claim 1, wherein the isolated peptide comprises~~ an amino acid sequence selected from the group consisting of SEQ ID NO: 11 to SEQ ID NO: 16~~SEQ ID NO: 17 to SEQ ID NO: 22~~, wherein said subject in need thereof has an angiogenesis-related disease selected from cancer and rheumatoid arthritis.

6. (Currently amended) The method of Claim 5, wherein the isolated peptide comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 17 to SEQ ID NO: 22~~SEQ ID NO: 11 to SEQ ID NO: 16~~.

7. (Currently Amended) A method for the treatment of an angiogenesis-related disease, comprising administering to a subject in need thereof an effective amount of:
an isolated peptide comprising an amino acid sequence represented by (I, D, E or K)-(E, A or Q)-L-(L, R or A)-(N, D or S)-(A, L, K or I)-(L or Y)-(R, N, L or K)-(Y or N)-H\- (M, I or G)-(V, L, Q or G)-(G, K, T or D)-(R, S, L or E)-(R, A, E or I)-(V, M, T or L)-(L, C or V)-(T, A, G or S), wherein the angiogenesis-related disease is selected from the group consisting of: cancer and rheumatoid arthritis.

8-12. (Canceled).

13. (Currently Amended). The method of Claim 7, wherein the isolated peptide comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 23 to SEQ ID NO: 26.

14. (Currently Amended) A method for the treatment of an angiogenesis-related disease, comprising administering to a subject in need thereof an effective amount of:
an isolated peptide comprising~~The method of Claim 7, wherein the isolated peptide comprises~~ an amino acid sequence selected from the group consisting of SEQ ID NO: 11 to SEQ ID NO: 16~~SEQ ID NO: 17 to SEQ ID NO: 22~~.

15. (Currently Amended) The method of Claim 14~~Claim 7~~, wherein the isolated peptide comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 17 to SEQ ID NO: 22~~SEQ ID NO: 11 to SEQ ID NO: 16~~.

16. (Previously presented) The method of claim 7, wherein the angiogenesis-related disease is cancer.

17. (Previously presented) The method of claim 7, wherein the angiogenesis-related disease is rheumatoid arthritis.

4. The following is an examiner's statement of reasons for allowance. The closest prior art of Kim *et al.* (*J. Biol. Chem.*, **2002**, *277*, 46159-65, published 09/21/2002, cited on the Information Disclosure Statement filed 10/03/2005) teaches a structure/function analysis of βig-h3, a TGF-β-induced matrix protein known to mediate adhesion of several cell types. Kim *et al.* teach that the four homologous fas-1 domains of βig-h3 mediate MRC-5 fibroblast adhesion. Deletion mutants of the fourth fas-1 domain revealed that the MRC-5 cell adhesion motif (denoted the YH motif) is located in amino acids 548-614. Experiments with substitution mutants showed that tyrosine 571, histidine 572, and their flanking leucine and isoleucine amino acids, which are all highly conserved in many fas-1 domains, are essential for mediating MRC-5 cell adhesion. A synthetic 18-amino acid peptide identical to instantly claimed SEQ ID NO: 18 encompassing these conserved amino acids could effectively block MRC-5 cell adhesion to βig-h3. The instantly claimed peptides are derived from the four fas-1 domains of βig-h3. SEQ ID NO: 26 corresponds to the active domain of the fourth fas-1 domain. SEQ ID NOs: 23-25 are the analogous domains of the first, second and third domains, respectively. Kim *et al.* do not teach a method of inhibiting endothelial cell migration and/or angiogenesis, or a method for treating angiogenesis-related diseases selected from cancer or rheumatoid arthritis using βig-h3, peptides derived from the fas-1 domains of βig-h3 or peptides comprising the YH motif and flanking hydrophobic residues. Further, the reference does not provide any motivation to use the peptides in the claimed methods. The prior art does not establish a predictable link between the function of inhibiting MRC-5 fibroblast adhesion and inhibiting endothelial cell migration, inhibiting angiogenesis or treating rheumatoid arthritis or cancer. Thus, the instantly claimed methods are both novel and unobvious over Kim *et al.*

5. The claimed methods are supported in the specification according to the provisions of 35 U.S.C. 112, first paragraph. SEQ ID NOs: 23-26 are derived from fas-1 domains I-IV, respectively, and each comprise the YH motif:

D-I	YH18	SEQ ID NO:23	IELLNALRYHMVGRRVLT
D-II	YH18	SEQ ID NO:24	EALRDLLNNHILKSAMCA
D-III	YH18	SEQ ID NO:25	DQLASKYLYHGQTLETLG
D-IV	YH18	SEQ ID NO:26	KELANILKYHIGDEILVS

These species have been demonstrated in the specification to inhibit endothelial cell adhesion in a dose-dependent manner (Fig. 5), inhibit endothelial cell migration in a dose-dependent manner (Fig. 7), and inhibit angiogenesis *in vitro* and in an *in vivo* Matrigel Plug assay (Fig. 8). A declaration submitted under 37 CFR 1.132 on 06/12/2007 provides evidence that the YH18 peptides are effective in a mouse model of rheumatoid arthritis. A declaration submitted under 37 CFR 1.132 on 07/07/2008 provides evidence that the fourth fas-1 domain, which comprises SEQ ID NO: 26, is effective in a mouse model of melanoma. A declaration submitted under 37 CFR 1.132 on 02/16/2009 provides evidence that βig-h3, which comprises SEQ ID NOs: 23-26, is effective a mouse model of lung cancer. Species SEQ ID NOs: 23-26 are representative of the broad peptide genus recited in claims 1 and 7 owing to the variability at each position. All options for residues Xaa1-Xaa16 are included in SEQ ID NOs: 23-26. SEQ ID NOs: 11-22, which do not fall within the genus of claims 1-7 but which are each fully defined sequences derived from this genus, contain substitution of the YH motif for AA, substitution of flanking bulky hydrophobic groups for S or both. Specifically, SEQ ID NOs: 12-14 and 18-20 include substitutions of Ser for flanking hydrophobic groups (see paragraph 0021 of the specification):

12	KESANSSKYHIGDEILVS
13	KELANILKYHSGDESSVS
14	KESANSSKYHSGDESSVS
18	GDAKESANSSKYHIGDEILVSGGIGALVR
19	GDAKELANILKYHSGDESSVSGGIGALVR

```
20    GDAKESANSSKYHSGDESSVSGGIGALVR
```

SEQ ID NOs: 11 and 17 include substitution of AA for the YH conserved sequence (see paragraph 0023 of the specification):

```
11        KELANILKAAIGDEILVS
17    GDAKELANILKAAIGDEILVSGGIGALVR
```

SEQ ID NOs: 15, 16, 21 and 22 include both types of substitutions (see paragraph 0024 of the specification):

```
15        KESANSSKAAIGDEILVS
16        KELANILKAASGDESSVS
21    GDAKESANSSKAAIGDEILVSGGIGALVR
22    GDAKELANILKAASGDESSVSGGIGALVR
```

These substitutions have been demonstrated in the specification to not disrupt the biological function of inhibiting endothelial cell adhesion (Fig. 4B). In light of the data presented in the original specification and declarations, and in light of the prior art which teaches the broad use of anti-angiogenic therapy in treating cancers (Zogakis *et al.* "General aspects of anti-angiogenesis and cancer therapy," *Exp. Opin. Biol. Ther.*, **2001**, *1*, 253-75, and Ribatti *et al.* "Angiogenesis and Anti-Angiogenesis in Hematological Malignancies," *J. Hematotherapy & Stem Cell Res.*, **2003**, *12*, 11-22), the method of inhibiting endothelial cell adhesion and migration, and angiogenesis in patients with rheumatoid arthritis and cancer, and methods of treating rheumatoid arthritis and cancer are enabled and described according to 35 U.S.C. 112, first paragraph. The conclusion of enablement is also supported by the following post-filing date art which is made of record: Kerbel "Antiangiogenic Therapy: A Universal Chemosensitization Strategy for Cancer?" *Science*, **2006**, *312*, 1171-1175.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA BRADLEY whose telephone number is (571)272-9044. The examiner can normally be reached on Monday-Thursday, 8:30 A.M. to 4:30 P.M.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

/Christina Marchetti Bradley/
Examiner, Art Unit 1654

cmb